II. REMARKS

Formal Matters

Claims 1-48 are pending after entry of the amendments set forth herein.

Claims 1-9 and 25-39 were examined and were rejected. Claims 10-25 were withdrawn from consideration.

Claims 1-4, 8, 9, 25, 29-34, 38, and 39 are amended. The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as acquiescence to any objection or rejection of any claim. Support for the amendments to claims 1-4, 8, 9, 25, 29-34, 38, and 39 is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary locations: claims 1, 8, 9, 25, 29, and 30: paragraph 0041; claims 31, 38, and 39: paragraph 0041, Table 5, page 27; and Figure 10; and claims 2, 3, and 32-34: paragraph 0044. Accordingly, no new matter is added by these amendments.

Claims 40-48 are added. Support for new claims 40-48 is found in the claims as originally filed, and throughout the specification, including the following exemplary locations: claims 40, 43, and 46: paragraph 0036; claims 41, 44, and 47: paragraph 0035; and claims 42, 45, and 48: paragraph 0038 . Accordingly, no new matter is added by these new claims.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Rejection under 35 U.S.C.§102(b)

Claims 1-3, 5, 6, 8, 9, 25-27, 29-33, 35, 36, 38, and 39 were rejected under 35 U.S.C.§102(b) as allegedly anticipated by Andya et al. (WO 97/04801).

The Office Action stated that WO 97/04801 teaches a stable lyophilized antie-HER2 antibody formulation comprising 1-20 mM histidine buffer, 30 mM mannitol, and 20 mM sucrose.

Claim 1 as amended recites a solid formulation comprising at least one antibody, and histidine in a concentration of from greater than 20 mM to about 60 mM. Claim 25 as amended recites a kit for preparing a solid formulation of stabilized antibody, the kit including a second container comprising a sufficient amount of histidine in solution to stabilize said antibody when said antibody is dried into a solid formulation, such that the concentration of histidine in the solid formulation is from greater than 20 mM to about 60 mM. Claim 31 as amended recites a liquid formulation comprising at least one antibody, and histidine in a concentration of from greater than 20 mM to about 60 mM. WO 97/04801

neither discloses nor suggests a formulation or a kit as claimed. WO 97/04801 states that the buffer concentration of protein solution can be from about 1 mM to about 20 mM; and states that exemplary buffers include histidine. WO 97/04801, page 15, lines 1-5. Accordingly, WO 97/04801 cannot anticipate any of claims 1, 25, and 31, or any claim depending therefrom.

Applicants submit that the rejection of claims 1-3, 5, 6, 8, 9, 25-27, 29-33, 35, 36, 38, and 39 under 35 U.S.C. §102(b) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejection under 35 U.S.C.§102(e)

Claims 1-3, 5, 6, 8, 9, 25-27, 29-33, 35, 36, 38, and 39 were rejected under 35 U.S.C.§102(e) as allegedly anticipated by Andya et al. (U.S. Patent No. 6,685,940).

The Office Action stated that U.S. Patent No. 6,685,940 teaches stable lyophilized anti-HER2 antibody comprising 1-20 mM histidine buffer, 38 mM mannitol, and 20 mM sucrose.

Claim 1 as amended recites a solid formulation comprising at least one antibody, and histidine in a concentration of from greater than 20 mM to about 60 mM. Claim 25 as amended recites a kit for preparing a solid formulation of stabilized antibody, the kit including a second container comprising a sufficient amount of histidine in solution to stabilize said antibody when said antibody is dried into a solid formulation, such that the concentration of histidine in the solid formulation is from greater than 20 mM to about 60 mM. Claim 31 as amended recites a liquid formulation comprising at least one antibody, and histidine in a concentration of from greater than 20 mM to about 60 mM. U.S. Patent No. 6,685,940 neither discloses nor suggests a formulation or a kit as claimed. U.S. Patent No. 6,685,940 states that the buffer concentration of protein solution can be from about 1 mM to about 20 mM; and states that exemplary buffers include histidine. U.S. Patent No. 6,685,940, column 15, lines 40-47. Accordingly, U.S. Patent No. 6,685,940 cannot anticipate any of claims 1, 25, and 31, or any claim depending therefrom.

Applicants submit that the rejection of claims 1-3, 5, 6, 8, 9, 25-27, 29-33, 35, 36, 38, and 39 under 35 U.S.C. §102(e) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejections under 35 U.S.C.§103(a)

Claims 1, 7, 25, 28, 31, and 37 were rejected under 35 U.S.C.§103(a) as allegedly unpatentable over WO 97/04801 or U.S. Patent No. 6,685,940 in view of Yang et al. ((1999) *Cancer Res.* 59:1236-1243; "Yang"). Claims 1, 4, 31, and 34 were rejected under 35 U.S.C.§103(a) as allegedly unpatentable over WO 97/04801 or U.S. Patent No. 6,685,940 in view of U.S. Patent No. 5,252,480.

Claims 1, 7, 25, 28, 31, and 37 over WO 97/04801 or U.S. Patent No. 6,685,940 in view of Yang

The Office Action stated that WO 97/04801 and U.S. Patent No. 6,685,940 do not teach fully human IgG2 monoclonal antibody. The Office Action stated that Yang teaches fully human IgG2 monoclonal antibody to the human EGF receptor. The Office Action concluded that one of ordinary skill in the art would have been motivated to combine fully human IgG2 monoclonal antibody as taught by Yang to prolong stability of a formulation upon storage and delivery. Applicants respectfully traverse the rejection.

As discussed above, neither WO 97/04801 nor U.S. Patent No. 6,685,940 discloses a formulation or a kit as claimed. Yang does not cure the deficiency of WO 97/04801 or U.S. Patent No. 6,685,940. Yang does not disclose or suggest any formulations comprising an antibody and histidine at the recited concentration. Accordingly, neither WO 97/04801 nor U.S. Patent No. 6,685,940, alone or in combination with Yang, renders any of claims 1, 7, 25, 28, 31, and 37 obvious.

Claims 1, 4, 31, and 34 over WO 97/04801 or U.S. Patent No. 6,685,940 in view of U.S. Patent No. 5,252,480

The Office Action stated that WO 97/04801 and U.S. Patent No. 6,685,940 do not teach arginine as an excipient. The Office Action stated that U.S. Patent No. 5,252,480 teaches that arginine has been used in antibody purification to prevent agglutination. The Office Action concluded that one of ordinary skill in the art would have been motivated to combine arginine as taught by U.S. Patent No. 5,252,480 to prevent agglutination of antibody in the antibody composition taught by WO 97/04801 and U.S. Patent No. 6,685,940. Applicants respectfully traverse the rejection.

As discussed above, neither WO 97/04801 nor U.S. Patent No. 6,685,940 discloses a formulation or a kit as claimed. U.S. Patent No. 5,252,480 does not cure the deficiency of WO 97/04801 or U.S. Patent No. 6,685,940. U.S. Patent No. 5,252,480 does not disclose or suggest any formulations comprising an antibody and histidine at the recited concentration. Accordingly, neither WO 97/04801 nor U.S. Patent No. 6,685,940, alone or in combination with U.S. Patent No. 5,252,480, renders any of claims 1, 7, 25, 28, 31, and 37 obvious.

Conclusion as to the rejections under 35 U.S.C.§103(a)

Applicants submit that the rejection of the claims discussed above under 35 U.S.C. §103(a) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number ABGX-007.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: Jan. 17, 2006

By: _____
Paula A. Borden
Registration No. 42,344

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, CA 94303
Telephone: (650) 327-3400
Facsimile: (650) 327-3231

F:\DOCUMENT\ABGX (Abgenix)\007\resp 09-14-05 OA.doc